

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

EXPRESS MAIL EL 990504794 US

No.:

APPLICANT(s): MAUL et al.

SERIAL NO.:

ART UNIT:

FILING DATE: Herewith

EXAMINER:

TITLE: SUBSTITUTED  $\gamma$ -LACTONE COMPOUNDS AS NMDA-  
ANTAGONISTS

ATTORNEY

DOCKET NO.: 785-011640-US (C01)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

(37 C.F.R. §1.97(b)(1))

Sir:

This Information Disclosure Statement is filed together with the above-identified patent application. Thus, a certification under 37 C.F.R. 1.97 (e) or fee under 37 C.F.R. 1.17(p) is not required for the information herein to be considered.

The following information is being disclosed to the Patent and Trademark Office as information that may be

material to the examination of the above-identified patent application.

The above-identified patent application claims priority to German Patent Application No. 10132725.0 filed July 5, 2001 and claims the benefit of PCT International Application No. PCT/EP02/07380 filed July 3, 2002. Applicants' attorney encloses a copy of a German Search Report issued on the priority German Patent Application No. 10132725.0 and a PCT International Search Report issued on the corresponding PCT International Application No. PCT/EP02/07380. The German Search Report cited "Synthesis And Pharmacological Properties of Derivatives Of  $\alpha$ -Amino- $\beta$ -(p-Chlorobenzoyl)-Propionic Acid And  $\alpha$ -Amino- $\gamma$ -(p-Chlorophenyl)-Tetrahydrofuran-2-One", Zabska et al., Polish J. Pharmacol. Pharm, 1991, 43, pp. 271-280.

The PCT International Search Report cited "Chemoenzymic Synthesis of Unnatural Amino Acids via Modified Claisen Rearrangement of Glycine Enolates. Approach to Morphine Synthesis", Gonzalez et al., Journal of Organic Chemistry, 1997, 62(5), pp. 1194-1195; "Friedel-Crafts Reactions Of  $\gamma$ -aryl- $\gamma$ -lactones", Plusquellec, Journal Chemical Research, SYNOP. 1982, pp. 46-47; "Reactions Of Glyoxylic Acid Derivatives With Olefins: Synthesis of .Alpha.-substituted.gamma.-lactones:", Plusquellec et al., Bulletin Societe Chimique De France, 1979, No. 9-10, PT 2, pp. 552-558; "A New Synthesis Of Amino Acids. II. Amidoalkylation of Olefins With Glyoxylic Acid Derivatives", Ben-Ishai et al., Tetrahedron Lett. 1975, Vol. 33, pp. 1533-1442; "Amino Acid Synthesis II. Amidoalkylation Of Olefins With Glyoxylic Acid Derivatives", Altman et al., Tetrahedron Lett. 1975, No. 43, PP. 3737-3740 and "Synthesis and Pharmacological

Study Of Some New Beta-(Dialkylaminomethyl)-Gamma-Butyrolact Ones and Their Tetrahydrofuran Analogues", Foscolos et al., Societa Chimica Italiana, No. 51, 1996, pp. 19-26.

Applicants' attorney also encloses copies of the following documents that were cited in the specification of the above-mentioned patent application: European Patent Application No. EP 0386839 B1; PCT International Publication Nos. WO 98/42673, WO 98/07704 and WO 97/12879; "Relationship Between the Inhibition Constant ( $K_i$ ) and the Concentration of Inhibitor Which Causes 50 per cent Inhibition ( $I_{50}$ ) of an Enzymatic Reaction", Cheng et al., Biochemical Pharmacology, Vol. 22, pp. 3099-3108, 1973; "2-Carboxytetrahydroquinolines. Conformational and Stereochemical Requirements for Antagonism of the Glycine Site on the NMDA Receptor, Carling et al., J. Med. Chem. 1992, 35, pp. 1942-1953; and [ $^3\text{H}$ ]MDL 105,519, a High-Affinity Radioligand for the N-Methyl-D-aspartate Receptor-Associated Glycine Recognition Site", Baron et al., Jnl of Pharm. And Experimental Therapeutics, 1996, pp. 62-68.

Pursuant to Sections 609 and 707.05(b) of the MPEP and 37 C.F.R. 1.97-1.99, the undersigned is bringing the following co-pending U.S. patent applications of which he is aware, to the attention of the Examiner in the above-identified application as they may be considered pertinent to the invention claimed in the above-identified application.

- (1) Express Mail No.: EL 990504542 US  
Mailing Date: January 5, 2004  
Title: Substituted 1-Aryl-But-3-Enylamine  
And 1-Aryl-But-2-Enylamine Compounds

Assignee: Grunenthal GmbH et al.

Attorney Docket No.: 785-011630-US (C01)

(2) Express Mail No.: EL 990504803 US

Mailing Date: January 5, 2004

Title: Substituted 1-Phenethylpiperidine  
Compounds Used As Inter Alia Analgesics

Assignee: Grunenthal GmbH

Attorney Docket No.: 785-011641-US (C01)

(4) Express Mail No.: EL 990504539 US

Mailing Date: January 5, 2004

Title: Use Of Substituted Gamma-Lactone Compounds  
As Pharmaceutical Preparations

Assignee: Grunenthal GmbH

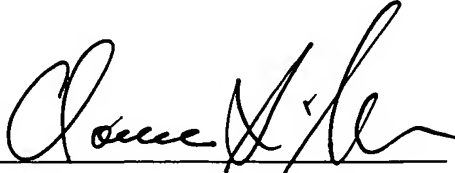
Attorney Docket No.: 785-011642-US (C01)

The filing of this Statement is not to be construed as a representation that a search has been made regarding the claimed invention (37 C.F.R. §1.97(g)) or that no other possible material information exists. In addition, the filing of this Information Disclosure Statement is not to be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability (37 C.F.R. §1.97(h)).

The Commissioner is hereby authorized to charge payment for any additional fees associated with this

communication or credit any over payment to Deposit  
Account No. 16-1350.

Respectfully submitted,



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5 January 2004  
Date

<b>INFORMATION DISCLOSURE CITATION FORM FOR PATENT APPLICATION (FORM PTO-1449) (Substitute)</b>			Docket No.: 785-011640-US(C01)  Applicant(s): MAUL et al.  Filing Date: Herewith		Serial No.:  Group:	
<b>U.S. PATENTS</b>						
Initials	Patent Number	Issue Date	Name	Class	Sub-class	Filing date
<b>U.S. PATENT PUBLICATIONS</b>						
Initials	Publication No.	Pub. Date	Name	Class	Sub-class	Filing Date
<b>FOREIGN PATENT DOCUMENTS</b>						
Initials	Document Number	Date	Country	Name	Translation? Yes/No/n/a	
	EP0386839 B1	1/15/97	Europe	Merck Sharp & Dohme Ltd.	n/a	
	WO 98/42673	10/1/98	PCT	Glaxo Wellcome S.P.A.	n/a	
	WO 98/07704	2/26/98	PCT	Glaxo Wellcome S.P.A.	n/a	
	WO 97/12879	4/10/97	PCT	BASF Aktiengesellschaft	no	
<b>OTHER DOCUMENTS (Title, Author, Date, Pages, Etc., if known)</b>						
	"Synthesis And Pharmacological Properties of Derivatives Of $\alpha$ -Amino- $\beta$ -(p-Chlorobenzoyl)-Propionic Acid And $\alpha$ -Amino- $\gamma$ -(p-Chlorophenyl)-Tetrahydrofuran-2-One", Zabska et al., Polish J. Pharmacol. Pharm, 1991, 43, pp. 271-280.					
	"Chemoenzymic Synthesis of Unnatural Amino Acids via Modified Claisen Rearrangement of Glycine Enolates. Approach to Morphine Synthesis", Gonzalez et al., Journal of Organic Chemistry, 1997, 62(5), pp. 1194-1195.					
	"Friedel-Crafts Reactions Of $\gamma$ -aryl- $\gamma$ -lactones", Plusquellec, Journal Chemical Research, SYNOP. 1982, pp. 46-47.					
	"Reactions Of Glyoxylic Acid Derivatives With Olefins: Synthesis of $\alpha$ -substituted $\gamma$ -lactones", Plusquellec et al., Bulletin Societe Chimique De France, 1979, No. 9-10, PT 2, pp. 552-558.					
	"A New Synthesis Of Amino Acids. II. Amidoalkylation of Olefins With Glyoxylic Acid Derivatives", Ben-Ishai et al., Tetrahedron Lett. 1975, Vol. 33, pp. 1533-1442.					
	"Amino Acid Synthesis II. Amidoalkylation Of Olefins With Glyoxylic Acid Derivatives", Altman et al., Tetrahedron Lett. 1975, No. 43, PP. 3737-3740.					
	"Synthesis and Pharmacological Study Of Some New Beta-(Dialkylaminomethyl)-Gamma-Butyrolact Ones and Their Tetrahydrofuran Analogues", Foscolos et al., Societa Chimica Italiana, No. 51, 1996, pp. 19-26.					
	"Relationship Between the Inhibition Constant ( $K_i$ ) and the Concentration of Inhibitor Which Causes 50 per cent Inhibition ( $I_{50}$ ) of an Enzymatic Reaction", Cheng et al., Biochemical Pharmacology, Vol. 22, pp. 3099-3108, 1973.					
	"2-Carboxytetrahydroquinolines. Conformational and Stereochemical Requirements for Antagonism of the Glycine Site on the NMDA Receptor, Carling et al., J. Med. Chem. 1992, 35, pp. 1942-1953.					
	"[ $^3$ H]MDL 105,519, a High-Affinity Radioligand for the N-Methyl-D-aspartate Receptor-Associated Glycine Recognition Site", Baron et al., Jnl of Pharm. And Experimental Therapeutics, 1996, pp. 62-68.					
Examiner's Signature:				Date Considered:		
Initial if reference was considered, whether or not citation is in conformance with MPEP. Mark through citation if not considered. Include a copy of this citation form with your next correspondence to the Applicant(s).						